BEFORE THE IOWA BOARD OF PHARMACY

RE:

Nonresident Pharmacy License of

SKYLINE PHARMACY INC.

License No. 4744 Respondent. CASE NO. 2017-72

NOTICE OF HEARING AND STATEMENT OF CHARGES

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Skyline Pharmacy Inc. ("Respondent"), 2123 2nd Ave, New York, NY 10029, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.6 and 35.7. Respondent's Iowa nonresident pharmacy license is currently delinquent, having expired on December 31, 2017.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on May 22, 2018, before the Board. The hearing shall begin at 9:00 a.m. and shall be located in the Board conference room located at the lowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines IA 50309.

<u>Answer.</u> Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.16. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board either by e-mail, if done in compliance with 657 IAC 35.17(2), to <u>Amanda.Woltz@iowa.gov</u>, or by mail/delivery to the following address: Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines IA 50309.

<u>Presiding Officer.</u> The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

<u>Prosecution.</u> The Office of Attorney General of Iowa is responsible for representing the public interest (the State) in this proceeding. Counsel for the State in this matter is Assistant Attorney General Laura Steffensmeier. Ms. Steffensmeier can be reached by phone at (515) 281-6690. Copies of pleadings should be provided to counsel for the State either by email to <u>Laura.Steffensmeier@ag.iowa.gov</u>, or by mail/delivery to the following address:

Laura Steffensmeier Assistant Attorney General Hoover State Office Building—2nd Floor 1305 E Walnut St Des Moines IA 50319

<u>Communications.</u> You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 155A, and 272C (2017).

<u>Legal Authority.</u> If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under lowa Code chapters 155A and 272C, and 657 IAC chapter 36.

<u>Default.</u> If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.27.

C. STATEMENT OF CHARGES

COUNT I FAILURE TO ENSURE LEGAL OPERATION

Respondent is charged with failure to ensure legal operation of the pharmacy in violation of 657 IAC 8.3(2), specifically by dispensing prescriptions and adding refills without prescriber authorization in violation of 657 IAC 8.19 and by failing to perform a complete drug use review in violation of 657 IAC 8.21 and 19.9(2), and may be disciplined pursuant to Iowa Code section 155A.13A(5)(d) and 657 IAC 19.11(5) and 36.6(21).

COUNT II FRAUD IN PROCURING A LICENSE

Respondent is charged with fraud in procuring a license, and may be disciplined pursuant to Iowa Code section 155A.13A(5)(d) and 657 IAC 19.11(5) and 36.6(1).

D. FACTUAL CIRCUMSTANCES

- 1. Respondent was initially licensed as a nonresident pharmacy in 2016. Respondent's nonresident pharmacy license number 4744 is currently delinquent, having expired on December 31, 2017.
- 2. Respondent dispensed prescriptions to lowa patients purportedly based on oral prescriptions, but the prescribers indicated the prescriptions had not in fact been authorized.
- 3. Respondent entered numerous refills for prescriptions that were not authorized by the prescriber.
- 4. Respondent did not communicate with patients to obtain information necessary to perform a proper drug utilization review prior to dispensing prescriptions, including information regarding patients' allergies, medical conditions, and current medications.
- 5. Respondent submitted applications to the Board in July 2016 and December 2016, both of which indicated the pharmacy did not engage in compounding.
- 6. Respondent was in fact compounding large batches of prescription creams in 2016 and 2017.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 35.24. To cancel a scheduled hearing, an executed settlement agreement must be received by the Board at least three (3) business days prior to the scheduled hearing. If you are interested in pursuing settlement in this matter, please contact the Assistant Attorney General identified above.

F. FINDING OF PROBABLE CAUSE

On this 14th day of March 2018, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

Chairperson

Iowa Board of Pharmacy

Sawan K Thunga

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).